sample and a 1:3,000 dilution of an unheated sample from the same lot shall be tested in parallel in the same rabbit, as prescribed in this paragraph. The vaccine is satisfactory if the potency of the heated sample is at least equal to that of the unheated sample.

(iv) *Heated dried vaccine.* Samples of dried vaccine from final containers taken at random shall be incubated at 35° to 37° C. for 30 days, after which a 1:1,000 dilution of the heated sample and a 1:3,000 dilution of an unheated sample from the same lot shall be tested in parallel in the same rabbit, as prescribed in this paragraph. The vaccine is satisfactory if the potency of the heated sample is at least equal to that of the unheated sample.

(b) *Pock counting in embryonated chicken eggs*—(1) *Dilutions.* Dilutions shall be made starting with no less than 0.5 ml. of the test vaccine and of the reference vaccine. The same diluent shall be used for all dilutions of both vaccines. The sample of vaccine in capillary tubes shall be obtained by pooling the contents of no less than 50 capillaries into a sterile vessel.

(2) *Inoculation of embryonated chicken eggs.* The chorioallantoic membranes of each of at least five embryonated chicken eggs shall be inoculated with 0.2 ml. for each virus dilution of the test vaccine and the reference vaccine, after which the eggs shall be incubated at 37° C. for 48 hours.

(3) *Estimation of potency.* Only membranes from living embryos shall be removed and the number of specific lesions thereon shall be counted and recorded. The number of pock forming units in 1.0 ml. of vaccine shall be calculated from the number of lesions, the dilution factor and the volume used, to determine the titer of the undiluted vaccine. The accuracy of the titration shall be confirmed in each test by performing simultaneously the same type of titration with the reference vaccine which shall demonstrate its assigned titer.

(4) *Potency requirements*—(i) *Vaccine intended for multiple pressure administration.* Vaccine intended for multiple pressure administration shall have a titer at least equivalent to the reference vaccine.

(ii) *Vaccine intended for jet injection.* Vaccine intended for administration by jet injector shall have a number of pock forming units in one human dose at least equivalent to that contained in 0.1 ml. of the reference vaccine diluted 1:30.

(iii) *Heated liquid vaccine.* Samples of liquid vaccine from final containers taken at random shall be incubated at 35° to 37° C. for at least 18 hours, after which the heated sample shall be tested in parallel with a sample of unheated vaccine of the same lot, as prescribed in this paragraph. The vaccine is satisfactory if the heated sample retains at least one tenth of the potency of the unheated sample.

(iv) *Heated dried vaccine.* Samples of dried vaccine from final containers taken at random shall be incubated at 35° to 37° C. for 30 days, after which the heated sample shall be tested in parallel with a sample of unheated vaccine of the same lot, as prescribed in this paragraph. The vaccine is satisfactory if the heated sample retains at least one tenth of the potency of the unheated sample.

§ 73.175 General requirements.

(a) *General safety.* Each lot of vaccine shall be tested for safety as prescribed in § 73.72 and shall meet the safety requirements of that section, except that for liquid Smallpox Vaccine distributed in capillaries, the test may be performed with a sample of bulk vaccine taken at the time of filling into final containers.

(b) *Preservative.* A preservative that meets the § 73.78 requirements may be used: *Provided,* That if the preservative is phenol, its concentration shall not exceed 0.5 percent.

(c) *Labeling.* In addition to complying with all other applicable labeling provisions of this part the package label shall bear the following:

(1) *Vaccine intended for jet injection.* (i) A conspicuous statement that the vaccine is intended for administration by jet injector.

(ii) A statement that the vaccine has been shown by appropriate test methods to contain not more than one organism per 100 doses or reference to an enclosed circular that contains such information, except that such a statement is not required for vaccine which meets the sterility requirements of § 73.73.

(2) *Vaccine intended for multiple pressure administration.* A statement that the vaccine has been shown by appropriate test methods to contain not more than 200 organisms per ml. or reference to a circular that contains such information, except that such a statement is not required for vaccine which meets the sterility requirements of § 73.73.

(d) *Samples; protocols; official release.* (1) For each lot of vaccine the following shall be submitted to the Director, Division of Biologics Standards, National Institutes of Health, Bethesda, Md. 20014.

(i) A protocol which consists of a summary of the history of manufacture of each filling lot including all results of each test for which test results are requested by the Director, Division of Biologics Standards.

(ii) Three hundred capillaries from the first filling of a lot of liquid vaccine, and two hundred capillaries from each subsequent filling.

(iii) Two 10 ml. samples of bulk liquid vaccine to be submitted along with the capillaries from the first filling and taken from the same vessel from which such capillaries were filled.

(iv) A sample from each drying, consisting of no less than the equivalent of 30 ml. of reconstituted vaccine, packaged in final containers, but in no event less than six filled final containers.

(2) Smallpox Vaccine shall not be issued by the manufacturer until notification of official release of the lot is received from the Director, Division of Biologics Standards.

§ 73.176 Equivalent methods.

Modification of any particular manufacturing method or procedure or the conditions under which it is conducted as set forth in additional standards relating to Smallpox Vaccine shall be permitted whenever the manufacturer presents evidence to demonstrate that such modification will provide equal or greater assurances of the safety, purity, and potency of the vaccine as the assurances provided by such standards, and the Director, National Institutes of Health, so finds and makes such finding a matter of official record.

(Sec. 215, 58 Stat. 690, as amended; 42 U.S.C. 216, sec. 351, 58 Stat. 702, as amended, 42 U.S.C. 262)

Dated: March 3, 1970.

ROBERT Q. MARSTON,
Director,
National Institutes of Health.

Approved: April 10, 1970.

ROBERT H. FINCH,
Secretary.

[F.R. Doc. 70-4674; Filed, Apr. 15, 1970; 8:49 a.m.]

DEPARTMENT OF TRANSPORTATION

Coast Guard

[33 CFR Part 110]

[CGFR 70-53]

MARCO ISLAND, MARCO RIVER, FLA.

Special Anchorage Area

1. Notice is hereby given that the Commandant, U.S. Coast Guard under authority of section 1, 30 Stat. 98, as amended (33 U.S.C. 180), section 6(g)(1)(B) of the Department of Transportation Act (80 Stat. 937, 49 U.S.C. 1655(g)(1)(B)) and 49 CFR 1.46(c)(2), is considering the addition of a § 110.74 to Part 110, Subpart A of Title 33, Code of Federal Regulations.

2. The proposed new section would establish and describe a Special Anchorage Area east of Captains Landing Docks in the Marco River at Marco Island, Collier County, Fla. In this special anchorage area, vessels not more than 65 feet in length, when at anchor, would not be required to carry or exhibit anchor lights.

3. It is proposed to amend Part 110 by adding a new § 110.74, reading as follows:

§ 110.74 Marco Island, Marco River, Fla.

Beginning at a point approximately 300 feet east of the Captains Landing Docks at latitude 25°58'04" N., longitude 81°43'31" W.; thence 108°, 450 feet; thence 198°, 900 feet; thence 288°, 450 feet; thence 018°, 900 feet to the point of beginning.

4. Interested persons may participate in this proposed rule making by submitting written data, views, arguments, or comments as they may desire on or before

May 11, 1970. All submissions should be made in writing to the Commander, 7th Coast Guard District, Room 1018, Federal Building, 51 Southwest First Avenue, Miami, Fla. 33130.

5. To expedite the handling of submissions regarding this proposal, it is requested that each submission be submitted in triplicate and state the subject to which it is directed; the specific wording recommended; the reason for the recommended change, and the name, address, and firm or organization, if any, of the person making the submission.

6. Each communication received within the time specified will be fully considered and evaluated before final action is taken on the proposal in this document. This proposal may be changed in light of the comments received. Copies of all written communications received will be available for examination by interested persons at the office of the Commander, 7th Coast Guard District, Room 1018, Federal Building, 51 Southwest First Avenue, Miami, Fla. 33130.

7. After the last date set for the submission of comments, the Commander, 7th Coast Guard District, will forward the record, including the original of all written submissions, and his recommendations with respect to the proposals and submissions received to the Commandant (OLE), U.S. Coast Guard, Washington, D.C. 20591. The Commandant will thereafter make a final determination with respect to this proposal.

Dated: April 9, 1970.

P. E. TRIMBLE,
Vice Admiral, U.S. Coast Guard,
Acting Commandant.

[F.R. Doc. 70-4634; Filed, Apr. 15, 1970; 8:46 a.m.]

Federal Aviation Administration

[14 CFR Part 71]

[Airspace Docket No. 70-SO-30]

TRANSITION AREA

Proposed Designation

The Federal Aviation Administration is considering an amendment to Part 71 of the Federal Aviation Regulations that would designate the Savannah, Tenn., transition area.

Interested persons may submit such written data, views, or arguments as they may desire. Communications should be submitted in triplicate to the Federal Aviation Administration, Area Manager, Memphis Area Office, Air Traffic Branch, Post Office Box 18097, Memphis, Tenn. 38118. All communications received within 30 days after publication of this notice in the FEDERAL REGISTER will be considered before action is taken on the proposed amendment. No hearing is contemplated at this time, but arrangements for informal conferences with Federal Aviation Administration officials may be made by contacting the Chief, Air Traffic Branch. Any data, views, or arguments presented during such conferences must also be submitted in writing in accordance with this notice in order to become part of the record for consideration. The proposal contained in this notice may be changed in the light of comments received.

The official docket will be available for examination by interested persons at the Federal Aviation Administration, Southern Region, Room 724, 3400 Whipple Street, East Point, Ga.

The Savannah transition area would be designated as:

> That airspace extending upward from 700 feet above the surface within a 7-mile radius of Savannah Municipal Airport.

The proposed designation is required to provide controlled airspace protection for IFR operations in climb from 700 to 1,200 feet above the surface and in descent from 1,500 to 1,000 feet above the surface. A prescribed instrument approach procedure to Savannah Municipal Airport, utilizing the Jacks Creek VORTAC, is proposed in conjunction with the designation of this transition area.

This amendment is proposed under the authority of section 307(a) of the Federal Aviation Act of 1958 (49 U.S.C. 1348(a)) and of section 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)).

Issued in East Point, Ga., on April 7, 1970.

GORDON A WILLIAMS, Jr.,
Acting Director, Southern Region.

[F.R. Doc. 70-4628; Filed, Apr. 15, 1970; 8:46 a.m.]

[14 CFR Part 91]

[Docket No. 10261; Notice No. 70-16]

CIVIL AIRCRAFT SONIC BOOM

Notice of Proposed Rule Making

The Federal Aviation Administration is considering the amendment of Part 91 of the Federal Aviation Regulations to afford the public protection from civil aircraft sonic boom in accordance with the requirements of section 611 of the Federal Aviation Act of 1958.

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the docket number and be submitted in duplicate to the Federal Aviation Administration, Office of the General Counsel, Attention: Rules Docket, GC-24, 800 Independence Avenue SW., Washington, D.C. 20590. All communications received on or before June 15, 1970, will be considered by the Administrator before taking action upon the proposed rule. The proposals contained in this notice may be changed in the light of comments and will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. Pursuant to Executive Order 11514, Protection and Enhancement of Environmental Quality (35 F.R. 4247), the comments of interested Federal, State and local agencies are specifically invited.

Section 611 of the Federal Aviation Act of 1958 (49 U.S.C. 1431, as added by Public Law 90-411, section 1, July 21, 1968, 83 Stat. 395) provides in pertinent part, that "in order to afford present and future relief and protection to the public from unnecessary aircraft noise and sonic boom, the Administrator of the Federal Aviation Administration, after consultation with the Secretary of Transportation * * * shall prescribe * * * such rules and regulations as he may find necessary to provide for the control and abatement of aircraft noise and sonic boom * * *."

Control of civil aircraft sonic boom is also supported by the National Environmental Policy Act of 1969 (Public Law 91-190, Jan. 1, 1970), which directs that the public laws of the United States shall be interpreted in accordance with the policies set forth in that Act, the specified national purpose of which is to promote efforts which will prevent or eliminate damage to the environment. This broad policy has been implemented by the President in Executive Order 11514 which directs the heads of Federal agencies to "monitor, evaluate, and control on a continuing basis their agencies' activities so as to protect and enhance the quality of the environment. Such activities shall include those directed to * * * enhancing the environment and those designed to accomplish other program objectives which may affect the quality of the environment. Agencies shall develop programs and measures to protect and enhance environmental quality * * *."

The FAA intends to insure that air transportation is channeled into forms in which its economic needs are compatible, not competitive, with the need to improve the environmental quality of the nation. This commitment reflects the following recent statement of the President in his State of the Union Address concerning the economic aspects of environmental quality control and the related need for leadership:

> The argument is increasingly heard that a fundamental contradiction has arisen between economic growth and the quality of life, so that to have one we must foresake the other. The answer is not to abandon growth, but to redirect it.

Sonic boom producing flights over populated areas within the United States are believed to be economically and technologically "unnecessary" as that word is used in section 611 of the Federal Aviation Act of 1958. Traffic demand studies have concluded that from 500 to 800 supersonic transport airplanes will be in operation by the year 1990. Available studies conclude that these expected traffic demands are sufficient to insure an economically viable supersonic transport, even assuming a sonic boom restriction of the kind proposed in this notice.

A restriction on sonic boom producing flights over populated areas is supported at this time by the inconclusive results of research concerning the effects of

sonic boom on the surface environment. For the past decade, the Federal Government, primarily through the Federal Aviation Administration, National Aeronautics and Space Administration, Environmental Science Services Administration, and the Department of Defense, has conducted research on sonic boom and its effects on people, animals, terrain, structures, and ecology in general. Although these efforts have had many significant technical and psychological results, they have not established a ceiling below which sonic booms caused by civil aircraft in commercial air transportation would be considered "tolerable" or "acceptable." Much is known about sonic boom generation, propagation, and variation due to differences in aircraft design. Much is also known concerning the area on the earth's surface affected by sonic booms associated with particular supersonic flights. However, it is known from the effects of the atmosphere and the effects of the ground environment that the sonic boom phenomenon has random elements. Prediction and evaluation of human response to sonic booms are exceedingly complex. In addition to the frequency and intensity of the physical stimulus, individual and community response also depends, in varying degrees, upon the immediate environment, the ambient noise conditions, and the experiences, attitudes, and opinions of those exposed as well as upon factors such as age and health. Consequently, formulating a reliable method for estimating the responses of individuals and communities to operational sonic boom exposures on the basis of the physical stimulus alone is most difficult at this time.

Based on the foregoing, and particularly in the absence of definitive conclusions that would warrant the establishment of a "tolerable" or "acceptable" sonic boom ceiling, a sonic boom restriction over land areas is believed to be a necessary environmental policy at this time, and to be economically reasonable and technologically practicable with respect to the coming generation of civil supersonic airplanes. However, in implementing such a restriction, three fundamental questions must be considered.

The first question in framing a sonic boom restriction concerns the geographic extent of the prohibition. Because of the changing patterns of population within the United States, it is not believed that a general regulatory definition of "populated" land areas can be established that would provide necessary protection from sonic boom. For this reason, the proposed rule in effect prohibits the operation of any civil aircraft within the United States at a speed that would cause a sonic boom to reach any part of the surface of the United States, except the surface of the territorial waters.

The second question concerns the kind of speed limit to be imposed. It is proposed generally to restrict all operations to speeds that insure that no sonic boom will reach the surface. Thus, protection of the environment from sonic boom, not prohibition of supersonic speeds per se, is the FAA's objective. This being the case, reasonable rule making should reflect the fact that it is possible to increase aircraft speed beyond Mach 1 (the speed of sound), under specific atmospheric conditions, and still not cause a sonic boom to reach the underlying terrain. Therefore, under the proposed rule, if the operator of a particular aircraft demonstrates, in a designated flight test area, that a specific Mach number greater than Mach 1 will not cause a sonic boom to reach the surface of the United States, except the territorial waters thereof, he would be able to obtain an authorization to exceed Mach 1 in operations conducted outside the designated flight test area. All conditions and limitations, necessary to insure that no sonic boom will reach the surface, would be specified in the authorization to exceed Mach 1 and would be enforceable in the same manner as any other regulation. These authorizations would be issued under the procedures in proposed § 91.55(c). This approach would reasonably permit all growth of supersonic air transportation that can be realized in practice without further cost to the environment, and, together with the sonic boom research encouraged and permitted under proposed § 91.55(b)(2), would provide incentive to eliminate the adverse effects of sonic boom where possible.

The third question concerns the extent to which sonic boom, consistent with the need to protect and enhance environmental quality, might properly be permitted to reach the surface. As proposed in § 91.55(b), there are three cases in which it is believed that this might be considered under closely controlled conditions.

The first case in which it may be in the public interest to permit a sonic boom to reach the surface concerns flights necessary to show compliance with the airworthiness provisions of the Federal Aviation Regulations or for aircraft development. For example, it may be necessary to operate prototype supersonic transport aircraft at high speeds within the United States to demonstrate their structural safety. Such tests are provided for in proposed § 91.55(b)(1). However, such flights would only be authorized in a designated flight test area.

The second case involves research and development flights necessary to determine the sonic boom characteristics of an aircraft, or to reduce or eliminate the effect of sonic boom on the surface environment. Considerable research, unilaterally and in collaboration with other interested governments, is being conducted to determine the responses of people, animals, terrain, structures, and ecology in general to sonic boom. Such research is necessary to insure that continuing aviation leadership does not involve further costs to the environment. For this reason, proposed § 91.55(b)(2) provides for any research and development flight that is "necessary to determine the sonic boom characteristics of the airplane, or is necessary to establish means of reducing or eliminating the effects of sonic boom." This research is also appropriate in order to find ways in which the continued growth of aviation can be made compatible with the objectives of section 2(b)(2) of the Department of Transportation Act which states that special effort should be made to preserve the natural beauty of the countryside and public parks and recreation lands, wildlife and waterfowl refuges, and historic sites. This research may also involve flight tests required by a Federal Aviation Regulation to determine the sonic boom characteristics of the airplane. This possibility is also provided for in proposed § 91.55(b)(2). Here again, all such flights would be limited to designated flight test areas.

The third case involves flights necessary to demonstrate the conditions and limitations under which speeds greater than Mach 1 will not cause a sonic boom to reach the surface. Clearly, such experimentation should be accomplished under conditions as closely controlled as those applicable to other research and development flights above Mach 1. This type of flight test is provided for in proposed § 91.55(b)(3). Such flights would also be limited to designated flight test areas. However, when the applicant has conservatively demonstrated the conditions and limitations necessary to insure that a speed above Mach 1 will not cause a sonic boom to reach the surface, and has demonstrated that such conditions conservatively represent all foreseeable operating conditions, an authorization to exceed Mach 1, containing those conditions and limitations, would be issued to an operator for operation outside the designated flight test area. The procedure for such approval is covered in proposed § 91.55(c).

For all flights conducted in a designated flight test area, conditions and limitations would be established under proposed § 91.55(d)(3) to insure that no sonic boom will reach the surface outside of that area.

In addition to requiring compliance with all conditions and limitations in an authorization to exceed Mach 1, the proposed rule would provide for denial of an application for such authorization, and for termination of such authorization, whenever the Administrator finds that such action is necessary to protect and enhance the environment (see proposed § 91.55 (e) and (f)).

In consideration of the foregoing, it is proposed to amend Part 91 of the Federal Aviation Regulations as follows:

1. Section 91.1(b)(3) would be amended to read as follows:

§ 91.1 Applicability.

* * * * *

(b) Each person operating a civil aircraft of U.S. registry outside of the United States shall—

* * * * *

(3) Except for §§ 91.15(b), 91.17, 91.38, 91.43, and 91.55, comply with Subparts A and C of this part so far as they are not inconsistent with applicable regulations of the foreign country where the aircraft is operated, or Annex 2 to the Convention on International Civil Aviation.

2. A new § 91.55 would be added to read as follows:

§ 91.55 Civil aircraft sonic boom.

(a) No person may operate a civil aircraft at a true flight Mach number greater than 1 except in compliance with the conditions and limitations in an authorization to exceed Mach 1 issued to the operator under this section.

(b) For a research and development flight in a designated flight test area an authorization to exceed Mach 1 may be issued if the applicant shows one or more of the following:

(1) The flight is necessary to show compliance with an airworthiness regulation or is necessary for aircraft development.

(2) The flight is necessary to determine the sonic boom characteristics of the airplane, or is necessary to establish means of reducing or eliminating the effects of sonic boom.

(3) The flight is necessary to demonstrate the conditions and limitations under which speeds greater than a true flight Mach number of 1 will not cause a sonic boom to reach the surface.

(c) For a flight outside of a designated flight test area, an authorization to exceed Mach 1 may be issued if the applicant shows conservatively that the flight will not cause a sonic boom to reach the surface of the United States, excluding the territorial waters thereof, when operated under conditions and limitations demonstrated under paragraph (b)(3) of this section, and shows that those conditions conservatively represent all foreseeable operating conditions.

(d) An application for an authorization to exceed Mach 1 must be made on a form and in a manner prescribed by the Administrator. In addtion, for an authorization covered by paragraph (b) of this section, each application must contain—

(1) Information showing that operation at speeds greater than Mach 1 is necessary to accomplish one of the purposes specified in paragraph (b) of this section;

(2) A description of the flight test area proposed by the applicant; and

(3) Conditions and limitations that ensure that no sonic boom will reach the surface outside of the designated flight test area.

(e) An application for an authorization to exceed Mach 1 may be denied if the Administrator finds that such action is necessary to protect and enhance the environment.

(f) An authorization to exceed Mach 1 is effective until it expires, or until it is surrendered, and may be terminated by the Administrator whenever he finds that such action is necessary to protect and enhance the environment.

This amendment is proposed under the authority of sections 307(c), 313(a), and 611 of the Federal Aviation Act of 1958 (49 U.S.C. 1348(c), 1354(a), and 1431), sections 2(b)(2) and 6(c) of the Department of Transportation Act (49 U.S.C. 1651(b)(2) and 1655(c)), Title I of the National Environmental Policy Act of 1969 (Public Law 91-190, Jan. 1, 1970), and Executive Order 11514 (Protection and Enhancement of Environmental Quality, Mar. 5, 1970).

Issued in Washington, D.C., on April 10, 1970.

JOHN O. POWERS,
Acting Director,
Office of Noise Abatement.

[F.R. Doc. 70-4629; Filed, Apr. 15, 1970; 8:46 a.m.]